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on March 29, 2006
Date of Deposit

Jasper W. Dockrey, Reg. No. 33,868
Name of applicant, assignee or
Registered Representative

Signature
March 29, 2006
Date of Signature

Case No. 1391/1555
Wrigley No. MAGBAR 01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MAXWELL et al.

Serial No.: 10/606,671

Filing Date: June 25, 2003

For: BREATH FRESHENING AND ORAL CLEANSING PRODUCT WITH MAGNOLIA BARK EXTRACT

Examiner:
Ruth A. Davis

Group Art Unit No.:
1761

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Declarant, Michael W.J. Dodds hereby declares as follows:

1. I am presently employed as a Principal Technology Scientist by Wm. Wrigley, Jr. Company at the Wrigley Global Innovation Center in Chicago, IL. I

hold a PhD. degree in Dental Science from the University of Liverpool, U.K., which was awarded in 1987. I have held my current position since 2002.

2. In my capacity as a research scientist, I identify, test, and develop innovative technologies for potential active ingredients in chewing gum and confectioneries. I also develop laboratory testing methods for plaque biofilm reduction, plaque pH, in vitro enamel microhardness testing, and protocols for germ kill testing and tooth whitening technologies. I have performed extensive research on the antimicrobial effects of a number of substances to determine their effectiveness at killing bacteria that cause bad breath and tooth decay.

3. At my direction, experiments were carried out to investigate the antimicrobial effects of Magnolia Bark Extract on bacteria present in human saliva. The saliva contained various species of bacteria including streptococci, actinomyces, and including S. mutans, F. nucleatum, and P. gingivalis. To investigate the antimicrobial effects of Magnolia Bark Extract on bacteria in the saliva the following experiments were performed

4. Biofilms were grown by incubation of saliva bacteria with saliva-treated hydroxyapatite (HA) discs in sterile 24-well cell culture plates. The media was supplemented with saliva (25% total volume) and the discs were transferred frequently during the growth phases to encourage growth of a dental plaque-like biofilm. The biofilms were allowed to develop for up to 72 hours. On days two and three of the experiment, the biofilms were exposed to the active ingredients three times a day for five minutes. The specific experimental steps are described below.

5. A mixed culture system that utilizes the bacteria from freshly-collected stimulated whole saliva was used. Saliva cell pellets were used to inoculate saliva-coated hydroxyapatite (S-HA) discs. The discs were placed in 24-well cell culture plates and incubated for up to 3 days. The biofilms were exposed

to actives on days 2 and 3 (starting at 18 hours), and quantified on day 4. The bacteria counts were determination using optical density (OD) measurements at 600 nm. Thus, the five experimental stages are: 1) pellicle formation; 2) bacterial attachment; 3) biofilm growth; 4) exposure to actives; and 5) bacterial enumeration. The five experimental stages are described in more detail below.

6. Pellicle formation: HA Discs were ultrasonically washed in deionized water and air-dried, then autoclaved. The discs were placed in a 24-well plate with 1 ml 50% sterile saliva for 2 hours and slowly agitated at room temperature. The plates were then placed on a thermomixer at 350 rpm. The saliva was suctioned and then the discs were transferred to fresh wells for bacterial attachment.

7. Bacterial attachment: the discs were placed into 1 ml saliva bacterial suspension (see below) at 300 rpm on the thermomixer and placed in an incubator at 37°C for 2 hours.

8. Biofilm growth: the bacterial suspension was removed, and the discs were transferred to fresh wells. One ml of supplemented saliva medium was added and the plate placed in the incubator for overnight incubation and for the duration of the experiment (up to 72 hours).

9. Exposure to active ingredients: Each morning on days 2 and 3, actives were prepared at the appropriate concentration in phosphate buffered saline (PBS). The PBS was used as a negative control and full strength Listerine® mouthwash was used as the positive control.

10. In addition to the negative and positive controls, the active ingredients used in the experiment included Magnolia Bark Extract. One ml of active

ingredients and controls were placed into fresh wells, and the discs were transferred to these wells for 5 minutes. The Listerine® control exposure was one minute, two times a day to mimic the standard mouth-rinse procedure. The exposure to active ingredients was carried out three times each day, at 8:00 a.m., 12:00 noon, and 4:00 p.m. After the timed exposure, the solution is removed and the discs washed twice with PBS, then transferred to fresh medium. The medium used during the day was Trypticase soy broth, with 0.5% sucrose.

11. Bacteria enumeration: On day 4 the discs were removed from the medium and placed into tubes with 2.5 ml of PBS, vortexed for 20 seconds, and then placed in an ultrasonic bath for another 20 seconds. The suspension was transferred into cuvettes and the OD measured at 600 nm.

12. The experimental results for the controls and the active ingredient Magnolia Bark Extract (MBE) and are shown below in Table 1.

TABLE 1

MBE and Cinnamic Aldehyde

OD and Percent Reduction vs. Control (PBS)

N=3 per group

Active Ingredient	OD at 600nm	Percent Reduction
Control (PBS)	0.286	-
Positive Control	0.070	76
MBE 1000ppm	0.118	59

13. The percent reduction appearing in Table 1 above for each test sample represents the percentage difference in the measured OD versus the OD for the negative control PBS. The data shown in Table 1 indicates that 1000 ppm

MBE is nearly as effective as the positive control at reducing the number of bacteria in the saliva samples.

14. I have reviewed I have reviewed U.S. Patent Application No. 10/606,671, titled "BREATH FRESHENING AND ORAL CLEANSING PRODUCT WITH MAGNOLIA BARK EXTRACT." I have also the amended claims presented in the response that accompanies this Declaration. I consider myself to be a person skilled in the art in the subject matter disclosed and claimed in the patent application. I have been asked to give opinions on the matters recited in this Declaration and I believe that I am qualified, by education and experience, to do so.

15. From the experimental results set forth above, it is my opinion that MBE is particularly effective against several types of bacterial in human saliva and, in particular, P. gingivalis and F. nucleatum.

16. From the results set forth above, it is my further opinion that MBE is particularly effective against P. gingivalis and F. nucleatum at concentrations greater than about 3.0 micrograms per milliliter of saliva in the oral cavity a human.

17. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

March 29, 2006
Date

Michael W.J. Dodds